



PATENT  
5142742001

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Scotti et al.  
Serial No. : 09/868,760  
Filed : June 21, 2001  
For : SERINE PROTEASE INHIBITORS  
Examiner : Y. Pak  
Group Art Unit : 1652

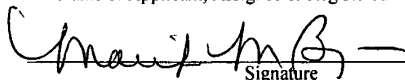
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Name of Applicant, Assignee or Registered Representative

  
Signature

October 30, 2002

Date of Signature

**RESPONSE TO OFFICE ACTION WITH REQUEST FOR  
WITHDRAWAL OF RESTRICTION REQUIREMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This is in response to the Office Action mailed on October 1, 2002, setting a one-month term for reply. The Office Action required restriction from among:

- Group I: claims 1-8 and 14-20, drawn to a serine protease inhibitor;
- Group II: claims 9-13, drawn to DNA encoding the protein of Group I, vector comprising said DNA and a host cell comprising said DNA; and
- Group III: claims 21-24, drawn to a method of producing the serine protease inhibitor.

Group II is elected with is elected with traverse for further examination in this application. Applicants retain the right to file divisional applications to non-elected subject matter.

Example 17 of Annex B Part 2 of the PCT Administrative Instructions (Appendix AI of the MPEP) provides:

Claim 1: Protein X

Claim 2: DNA sequence encoding protein X.

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

The polynucleotide in the Group II claims encodes the polypeptide of the Group I claims, and, according to Example 17, have unity of invention. Therefore, these claims should be searched and examined in the same application, as is dictated by the PCT Administrative Instructions. Page 2 of the Office Action states that "the DNA molecule of Group II (claim 10) can encode a polypeptide not having the structure of the protein of Group I." This is clearly not the case. Claim 9, upon which claim 10 depends, recites "[a] polynucleotide encoding a protein or fragment as claimed in any of claims 1-8." Thus, the very definition of the Group II DNA molecules is predicated upon the Group I polypeptides.

Further, Example 1 of Annex B Part 2 of the PCT Administrative Instructions (Appendix AI of the MPEP) provides, in part:

Claim 1: A method of manufacturing chemical substance X.

Claim 2: Substance X.

Unity exists between claims 1 and 2. The special technical feature common to the claims is substance X.

The Group III claims, involving methods of making serine protease inhibitor, and the Group I claims, to the serine protease inhibitor, have unity of invention according to the PCT Administrative Instructions and should be searched and examined in the same application.

Therefore, Groups I and II should be rejoined based on Example 17, and Groups I and III should be rejoined based on Example 1 of the PCT Administrative Instructions. Group I contains linking claims that unite all three groups.

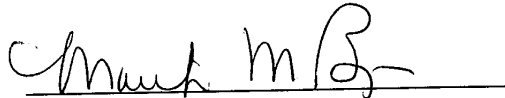
Under PCT Rule 13.2, all claims must share the same special technical feature. The technical feature uniting the three groups of claims is that they all relate serine protease inhibitors, as pointed out by the Examiner on page 2 of the Office Action. In the very next sentence, she contradicts herself, stating that Groups I-III do not share a technical feature. It is

submitted, that the claims of all three groups do, in fact, share a technical feature, as stated in the Office Action and should thus be examined in the same application.

The Office Action further required election of a single nucleic acid sequence. SEQ ID NO:6 is elected with traverse. As a traverse, it should be noted that the molecules represented by SEQ ID NOs:6 and 8, and DNA molecules encoding the polypeptides represented by SEQ ID NOs:1-5, represent members of a single structurally and functionally related genus - serine protease inhibitors. They should not be construed to be patentably distinct inventions.

Enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since unity of invention exists, and there are clear relationships between the claims of all Groups. Reconsideration and withdrawal of the requirement for restriction and early and favorable examination, on the merits, of all of the claimed subject matter are requested.

Respectfully submitted,  
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